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CLOSED VIAL FILL SYSTEM FOR ASEPTIC DISPENSING

This application claims priority to U.S. Provisional Application No. 61/428,041 entitled "CLOSED VIAL FILL SYSTEM FOR ASEPTIC DISPENSING" filed on Dec. 29, 2010, and to U.S. Provisional Application No. 61/508,409 entitled "CLOSED VIAL FILL SYSTEM FOR ASEPTIC DISPENSING" filed on Jul. 15, 2011, the entirety of each is incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

Aspects of the present invention relate generally to a vial filling system and methods of use thereof. More specifically, particular aspects of the invention relate to a device for filling vials with measured quantities of a substance or substances, for use in the diagnostic imaging field of nuclear medicine.

2. Description of Related Art

Positron Emission Tomography (PET) is a nuclear medicine imaging technique in which a positron-emitting radionuclide, such as carbon-11, nitrogen-13, oxygen-15 or fluorine-18, is chemically incorporated into a compound normally used by the body, such as glucose, water or ammonia. The compound may then be injected into a patient, for example, so that a targeted biological process of the body will naturally distribute the compound. The radionuclide serves as a tracer for subsequent imaging by a scanner, wherein the decay of the radioisotope produces a record of the concentration of the tissue in the area being imaged, providing a practitioner detailed views of a targeted anatomy in a patient when combined with a Computerized Tomography (CT) study (CT/PET).

Nuclear medicine requires special considerations in the preparation, handling and delivery of radioactive materials for use in various medical procedures. For example, fluorodeoxyglucose (FDG), an analogue of glucose, is commonly used for the chemical incorporation of the radioisotope fluorine-18 for use in PET procedures. Production of the radioisotope fluorine-18 for use in the radiopharmaceutical is often difficult and/or expensive, requiring specialized equipment such as a cyclotron. Thus, the production of the radioisotope often occurs at a remote facility by a third party, from which the hospital or lab receives patient doses ready to inject. Even if the radioisotope happens to be produced on site, final production of the radiopharmaceuticals used in many diagnostic imaging procedures requires manual preparation in a special aseptic environment to ensure a safe injectable product free of environmental contaminants and for precise accounting of the radioactive nature of the radionuclide to be used in the radiopharmaceutical for each procedure, recognizing that the bulk radionuclide product is continuously decaying over time. Furthermore, during preparation of the radiopharmaceutical, the radiopharmacists must be shielded from the ionizing radiation of the radioisotope, and the purity of the radiopharmaceutical must be ensured by filtering and/or avoiding contamination through contact with particles in the air, on a surface, and/or when mixing with a diluting liquid, for example. Thus, because of the short half-life of the radionuclide, the efficient scheduling of patients, for example, along with a safe and efficient preparation of the radiopharmaceutical by technicians is critical in order to avoid wasting the prepared bulk product of the radionuclide.

To create an aseptic environment for the production of pharmaceuticals, a special clean air "canopy" or laminar flow hood, for example, is often used, wherein high-efficiency

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particulate air (HEPA) filters are provided in conjunction with a closed containment structure, within which the pharmaceuticals can be prepared. The interior environment of the containment structure is closely monitored, for example, by a particle counter, to determine the airborne particulate density of possible contaminants. However, when preparation of the pharmaceutical includes a radioactive material, the aseptic environment described above must also be shielded. It is very difficult to combine a shielded enclosure with a filtered environment without compromising the ability to produce a radiopharmaceutical compound efficiently.

Furthermore, present procedures for dispensing radiopharmaceuticals into final product vials for delivery to one or more patients often involves accessing and extracting the radionuclide product for an individual procedure from a bulk product vial. The bulk product vial may already contain other components, such as sterile water for injection of the radioactive component, or other components may be added to the bulk product vial as necessary or contained/added to each individual vial for mixing with the radionuclide. The bulk product vial, which is contained in a shielded enclosure to minimize exposure of the technician to radiation, is typically accessed by one or more technicians using a syringe to puncture a resealable membrane of the bulk product vial in order to extract a quantity of the radioactive component. Thus, each time a quantity of the radioactive component is extracted in this manner, there is a chance that contaminants can be introduced into the bulk product vial as the syringe punctures and/or is removed from the bulk product vial.

To decrease the chance of contamination by multiple punctures of a syringe, it has been proposed to use an automated syringe that automatically draws material from the bulk product vial into each of the individual vials. However, even if a syringe pump, for example, reduces the chance of contamination by reducing the number of times the bulk product vial membrane is punctured, each plunge of the syringe after the initial plunge risks contamination through airborne particles, for example, being drawn in through the back of the syringe.

Thus, the use of syringes in the preparation of a radiopharmaceutical has inherent drawbacks in preserving the quality and accuracy of a dose to be dispensed for use in a medical procedure, for example. Additionally, syringes can limit the size of a dose being dispensed. For example, when the goal is to withdraw the product from the bulk product vial with one plunge in order to reduce the risk of contamination, a requirement for a 100 ml dose of a product would require the use of an unusually large syringe.

Accordingly, there is a need for a system and associated methods for providing an aseptic, closed path vial fill system that may overcome one or more of the problems discussed above. In particular, there is a need for improved vial filling systems that may promote a more efficient setup and procedure for dispensing radiopharmaceuticals in a safe and effective manner that guarantees the integrity of the radiopharmaceutical every time.

SUMMARY OF THE INVENTION

In accordance with aspects of the present invention, a closed path vial fill system may include a bulk product vial, a peristaltic pump operated by a stepper motor, a dispensing manifold assembly to which may be coupled to at least one final product vial, an optional quality check station, and an optional waste collection system. A control system may be integrated into the system to provide automated control of various aspects of the radiopharmaceutical dispensing process. The system is used to aseptically dispense finished